SUPPORT FOR THE AMENDMENTS

Applicants have amended Claim 11, to change "all or part of said internal surface is a material selected from the group consisting of stainless steel and anodized aluminum" to "all or part of said internal surface is anodized aluminum." Accordingly, support for amended Claim 11 can be found in the same claim, as previously presented. Claims 20 and 31 have been amended for clarity and to properly depend from Claim 11. Support for amended Claims 20 and 31 can be found in the same claims, as previously presented. Claims 15 and 42-44 have been amended for clarity. Support for amended Claims 15 and 42-44 can be found in the same claims, as previously presented.

No new matter has been added. Claims 11-17 and 20-44 are active in this application.

REMARKS

Present Claims 11-17 and 20-44 relate to pressurized metered dose inhalers ("MDIs"), which contain a solution comprising an active ingredient, a hydrofluorocarbon propellant, and a cosolvent, wherein the inhalers have an internal surface and all or part of the internal surface is anodized aluminum.

The inventors have surprisingly found that the presently claimed MDIs unexpectedly reduce the chemical degradation of the active ingredient contained in the MDI. The cited references contain no disclosure or suggestion of the presently claimed MDIs. Moreover, these references contain no teaching which would suggest the improved chemical stability of the active ingredient contained in the presently claimed MDIs. Accordingly, these references cannot affect the patentability of the present claims.

The rejection of Claims 11-44 under 35 U.S.C. § 103(a) in view of U.S. Patent No. 5,676,930 (Jager et al.) in view of U.S. Patent No. 6,253,762 (Britto et al.) is respectfully traversed. Specifically, as explained in more detail below, neither of the cited references

discloses nor suggests any MDI in which all or part of the internal surface is anodized aluminum.

Jager et al. discloses certain stabilized medicinal aerosol solution formulations. However, as conceded on page 7 of the Office Action, this reference neither discloses nor suggests any MDIs in which all or part of said internal surface is anodized aluminum.

Britto et al. discloses certain MDIs in which all or part of the internal surface is coated with one or more fluorocarbon polymers, optionally in combination with one or more non-fluorocarbon polymers, for dispensing an inhalation drug formulation comprising fluticasone propionate.

On page 7 of the Office Action, the position is taken that Britto et al. discloses an MDI with "an inhaler internal surface material selected from the group consisting of stainless steel and anodized aluminum coated with fluorocarbon polymer." However, this assertion is not correct. Britto et al. does not disclose any MDI in which all or part of said internal surface is ***anodized*** aluminum.

In fact, a word search of the searchable versions of both Jager et al. and Britto et al. on the USPTO web page shows that the word "***anodized***" is not found in either of these references.

Thus, even in combination, Jager et al. and Britto et al. fail to suggest any MDI in which all or part of said internal surface is ***anodized*** aluminum.

In contrast, presently amended Claim 11 requires that the "inhaler has an internal surface and all or part of said internal surface is ***anodized*** aluminum."

Since the combined teachings of Jager et al. and Britto et al. are silent in regard to ***anodized*** aluminum, these references cannot create a *prima facie* case of obviousness against the present claims.

For this reason alone, the rejection should be withdrawn.

In any event, as clearly stated in column 1, lines 21-45, the drug, fluticasone propionate, is present in the inhalation formulation of Britto et al. as a finely divided powder ***suspended*** in a liquefied propellant (*see also*, the Examples at cols. 7 to 10). Britto et al. discloses that the technical problem in this kind of suspension formulation is that:

> Some aerosol drugs tend to adhere to the inner surfaces, i.e., walls of the can, valves, and caps, of the MDI. This can lead to the patient getting significantly less than the prescribed amount of drug upon each activation of the MDI.

See, col. 1, lines 55-58.

The solution to this problem as proposed in Brittot et al. is to use an MDI in which the interior surface is coated with a fluorocarbon polymer (*see*, col. 2, lines 1-9).

Thus, Britto et al. is only concerned with a problem which is specific to suspensions and does not disclose any MDI which contain a ***solution*** of an active agent.

In sharp contrast, the present claims explicitly recite that the MDI contains "a ***solution*** comprising an active ingredient." As explained above, the inventors have discovered that the presently claimed MDI unexpectedly afford a dramatic improvement in the chemical stability of the active ingredient in the solution contained in the MDI.

Thus, the problem solved by the presently claimed MDIs is quite distinct from that of Britto et al. As explained on page 3, lines 4-6, of the present specification, "the widespread use of [HFA solution] formulations is limited by their chemical instability, causing the formation of degradation products." As further explained on pages 4-6 of the present specification, the inventors have found that:

> the chemical stability problems of active ingredients in solution in HFA propellants can be eliminated by storing and delivering said composition employing metered-dose inhalers having part or all of their internal metallic surfaces consisting of stainless steel, anodized aluminum or lined with an inert organic coating.

> The preferred material for the aerosol cans is anodized aluminum.
>
> *See*, page 4, line 26, to page 5, line 5.
>
> * * *
>
> The inhalers according to the invention effectively prevent the chemical degradation of the active ingredient.
>
> See, page 5, lines 26-28.
>
> * * *
>
> Active ingredients which may be used in the aerosol compositions to be dispensed with the inhalers of the invention are any ingredient which can be administered by inhalation and which meets ***problems of chemical stability in solution in HFA propellants*** giving rise to a decomposition when stored in conventional materials cans and in particular in aluminum cans.
>
> See, page 6, line 28, to page 7, line 7, emphasis added.

There is no disclosure of the problem of chemical stability Britto et al. At most, one would look to the disclosure of Britto et al. to address the specific disclosed problem with ***suspensions***. Since the present claims are directed toward MDI which contain a ***solution*** of the active ingredient, one of skill in the art would not look to Britto et al. to address the problem of chemical stability encountered with such solutions.

For all of these reasons, the rejection should be withdrawn.

The rejection of Claims 11-19 under the judicially-created doctrine of obviousness-type double patenting in view of Claims 22, 27, 31, 35-37, 41, and 42 of U.S. Patent No. 7,018,618 (Lewis et al. '618) and the rejection of Claims 20-44 under the judicially-created doctrine of obviousness-type double patenting in view of Claims 22, 27, 31, 35-37, 41, and 42 of Lewis et al. '618 in view of Jager et al. are respectfully traversed. Quite simply, none of the claims of Lewis et al. '618, either taken alone or in view of Jager et al., suggest any MDI in which all or part of said internal surface is ***anodized*** aluminum.

Accordingly, the rejections are improper and should be withdrawn.

The rejection of Claims 11-20 under the judicially-created doctrine of obviousness-type double patenting in view of Claims 1, 6, 7, 10, 14, 15, 19, and 22-29 of U.S. Patent No. 6,713,047 (Lewis et al. '047) and the rejection of Claims 21-44 under the judicially-created doctrine of obviousness-type double patenting in view of Claims 1, 6, 7, 10, 14, 15, 19, and 22-29 of Lewis et al. '047 in view of Jager et al. are being obviated by the filing herewith of a duly executed Terminal Disclaimer.

Accordingly, the rejections should be withdrawn.

The provisional rejection of Claims 11-23, 26, 28, 31-34, 37, 39, 42, and 43 under the judicially-created doctrine of obviousness-type double patenting in view of Claims 1-3, 6, 8, 10, and 11 of co-pending U.S. Patent Application No. 11/289,479 ("the '479 application") and the provisional rejection of Claims 11 and 15-17 under the judicially-created doctrine of obviousness-type double patenting in view of Claims 1, 12, 14, 17, 18, and 20 of co-pending U.S. Patent Application No. 10/505,861 ("the '861 application") are respectfully traversed, on the ground that these application both have filing dates which are later than that of the present application and, in view of the present amendments and remarks, these provisional rejections are the only rejections remaining in the present application.

Accordingly, the rejections should be withdrawn.

Applicants submit that the application is now in condition for allowance, and early notification of such action is earnestly solicited.

Respectfully submitted,

OBLON, SPIVAK, McCLELLAND,
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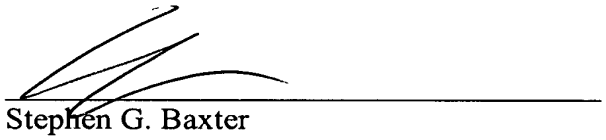

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